



GE Healthcare  
% Mr. Bryan Behn  
Regulatory Affairs Director  
9900 Innovation Drive  
WAUWATOSA WI 53226

October 22, 2020

Re: K201768  
Trade/Device Name: Voluson E10  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: Class II  
Product Code: IYN, IYO, ITX  
Dated: September 16, 2020  
Received: September 17, 2020

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

<https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.  
Director  
Division of Radiological Health  
OHT7: Office of In Vitro Diagnostics  
and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K201768

Device Name

Voluson E10

### Indications for Use (Describe)

The device is a general purpose ultrasound system intended for use by qualified and trained healthcare professionals. Specific clinical applications remain the same as previously cleared: Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid etc.); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Peripheral Vascular; Transvaginal (including GYN); Transrectal

Modes of operation include: B, M, PW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD.

The Voluson E10 is intended to be used in a hospital or medical clinic.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K201768

GE Healthcare

510(k) Premarket Notification Submission

**510(k) Summary**

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: June 24, 2020

Submitter: GE Healthcare [GE Healthcare Austria GmbH & Co OG]  
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Zipf, Austria 4871

Primary Contact Bryan Behn  
Person: Regulatory Affairs Director  
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F:(+43)7682 3800-47

Device: Trade Voluson E10  
Name: Models: Voluson E10

Common/Usual Ultrasound system  
Name:

Classification Names: Class II  
Product Code: Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550, 90-IYN  
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO  
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Primary Predicate K192159 Voluson E6\_E8\_E10 Diagnostic Ultrasound System  
Device(s):

Secondary Predicate  
Device(s): K173555 LOGIQ E10 Diagnostic Ultrasound System  
K181685 Vivid E95 Diagnostic Ultrasound System



## GE Healthcare

### 510(k) Premarket Notification Submission

Device Description: The systems are full-featured Track 3 ultrasound systems, primarily for general radiology use and specialized for OB/GYN with particular features for real-time 3D/4D acquisition. They consist of a mobile console with keyboard control panel; color LCD/TFT touch panel, color video display and optional image storage and printing devices. They provide high performance ultrasound imaging and analysis and have comprehensive networking and DICOM capability. They utilize a variety of linear, curved linear, matrix phased array transducers including mechanical and electronic scanning transducers, which provide highly accurate real-time three-dimensional imaging supporting all standard acquisition modes.

Intended Use: The device is a general-purpose ultrasound system intended for use by qualified and trained healthcare professionals. Specific clinical applications remain the same as previously cleared: Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid etc.); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Peripheral Vascular; Transvaginal (including GYN); Transrectal

Modes of operation include: B, M, PW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD. The Voluson E10 is intended to be used in a hospital or medical clinic.

Technology: The Voluson E Series (Voluson E10) employs the same fundamental scientific technology as its predicate devices.

#### Determination of Comparison to Predicates

##### Substantial Equivalence:

The proposed Voluson E10 is substantially equivalent to the predicate devices with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed Voluson E10 and predicate Voluson E Series systems have the same clinical intended use.
- The proposed Voluson E10 and predicate Voluson E Series systems have the same imaging modes.



## GE Healthcare 510(k) Premarket Notification Submission

- The proposed Voluson E10 and predicate Voluson E Series systems transducers are equivalent. Two new transducers 12S-D and eM6CG3 were added and 10 transducers removed to the proposed system.
- There is no change to the system indications for use.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The proposed Voluson E10 and predicate Voluson E Series systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed Voluson E10 and predicate systems have been designed in compliance with approved electrical and physical safety standards.
- There proposed Voluson E10 and predicate Voluson E series Software Features are equivalent. Some minor improvements to the existing Software features have been implemented into the proposed system.
- The proposed Voluson E10 adds additional measurements of existing software feature **SonoBiometry** (workflow improvement).
- The proposed Voluson E10 adds Image Analysis of existing software feature **Scan Assistant** (workflow improvement).
- The proposed Voluson E10 adds **Fetal Heart Screening** (workflow improvement).
- The proposed Voluson E10 adds functionality check of probe crystals/elements to existing e-PAT (electronic probe assessment tool) acc. FDA guideline (modified for customer access add.to previous service tool).



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Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. The Voluson E Series and its applications comply with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/(R)2012 And A1:2012
- IEC60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests, 2014
- IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2015
- ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition, 2009
- ISO14971, Application of risk management to medical devices: Second edition 2007
- NEMA PS 3.1 - 3.20 (2016), Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Final Acceptance Testing (Validation)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Voluson E10 did not require



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clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Voluson E10 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).